UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* Track One Cases	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

POSITION STATEMENT REGARDING PLAINTIFFS' CT1B CLAIMS

Pursuant to the Court's Order dated January 31, 2020, Plaintiffs submit the following Position Statement setting forth the claims they intend to assert at trial, the theories of liability they intend to pursue, and how they intend to prove them. Order at 1 (Dkt. # 3116).[1] Put simply, Defendants failed to protect against diversion in both their wholesale distribution and their retail dispensing of dangerous, addictive opioid prescription drugs. At both the wholesale and the retail level, Defendants had available to them a wealth of data that raised suspicions or "red flags" suggestive of diversion. Indeed, because these Defendants were shipping drugs to their own pharmacies, they had complete visibility into the supply chain and thus were uniquely situated to detect and prevent diversion. Yet,

[1] Recognizing the importance of aiding in the case management of these proceedings, Plaintiffs here provide their theories of the case based on the information currently available. Plaintiffs, however, note that they do so in the absence of a motion from Defendants challenging the legal basis for their claims. Defendants have not elected to file the motions to dismiss invited by the Court regarding plaintiffs' dispensing claims, nor have they yet filed dispositive motions related specifically to the CT1b proceeding. Consequently, while plaintiffs provide this statement in good faith, plaintiffs' responses to Defendants' legal challenges of their claims, beyond those previously issued and decided in this case, will be forthcoming when such motions are filed.

at both the wholesale and retail level, Defendants used the data they had for their own business purposes (to increase sales and profits), but did not use it to aid in detecting and stopping diversion. At both the wholesale and the retail level, Defendants failed to design, implement, or follow policies that would have identified and investigated suspicious orders or red-flag prescriptions. As a result, Defendants shipped suspicious orders and filled red-flag prescriptions without engaging in the due diligence necessary to determine that diversion was unlikely or that the prescriptions were legitimate. Defendants' shipment of suspicious orders, and their dispensing of red-flag prescriptions, without appropriate due diligence violated the federal Controlled Substances Act ("CSA") and in particular, violated state and federal laws and regulations applicable to wholesale and retail sales of prescription opioids. As a result of their statutory and regulatory violations, Defendants created an absolute public nuisance in the Plaintiff Counties.

As described below, Plaintiffs intend to rely upon analysis of the aggregate data available to Defendants at the time suspicions and red flags would have arisen, which will show that Defendants turned a blind eye to and routinely shipped suspicious orders and filled red-flag prescriptions without regard to the risks of diversion. Plaintiffs will further show that this course of conduct caused and/or substantially contributed to the public nuisance arising from diversion of opioids.

A. Claims

In accordance with this Court's instruction, Plaintiffs acknowledge they intend to try the Sixth and Eleventh Claims for Relief, set forth in the Summit and Cuyahoga operative complaints,[2] for

[2] Plaintiffs' Summit and Cuyahoga's Third Amended Complaints, were filed on March 21, 2019 and May 10, 2019 respectively. Both incorporate Amendments by Interlineation were filed on November 20, 2019. Dkt. No. 2943 (Summit); Dkt. No. 2944 (Cuyahoga).

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Absolute Public Nuisance and Civil Conspiracy respectively, against all pending Defendants.[3] Plaintiffs have agreed to dismiss all remaining claims without prejudice.

B. Trial Structure

As indicated during the January 29, 2020 CT1b case management conference, Plaintiffs anticipate that the Court intends to bifurcate the trial (and any expert discovery related to remedies), such that a jury will first determine whether Defendants are liable for the two claims asserted, and, if the jury finds that any or all Defendants substantially contributed to the existence of a public nuisance, and/or that the Defendants are liable for civil conspiracy, the Court will then determine the remedy at a later date.

C. Theory of Liability

Plaintiffs advance a single theory of the case against the Pharmacy Chains with respect to their distribution and dispensing activities: Defendants created an absolute public nuisance through their violations of the federal Controlled Substance Act and related state laws and regulations, which prohibit distribution or sale of controlled substances by any person other than as set forth in the statute and regulations. In particular, under the CSA, distributors may not ship suspicious orders without proper due diligence to determine that diversion is not likely, and pharmacies may not fill prescriptions in the presence of unresolved red flags about the legitimacy of the prescription or the

[3] The defendant families against whom claims are currently pending are: CVS, Rite Aid, Walgreens, Walmart, HBC/Giant Eagle, and DDM.

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prescriber.[4] Pharmacy Chain Defendants acted in both capacities, and Plaintiffs will show that they failed to comply with either requirement. Plaintiffs will further show that these statutory and regulatory failures caused a public nuisance in Plaintiffs' communities.

By engaging in the distribution and sale of opioids, buying and selling known dangerous and addictive drugs that are controlled by laws specifically meant to protect against diversion, Defendants obligated themselves to comply with the provisions of the CSA and vigilantly guard against diversion. Under the CSA, registrants are obliged to "provide effective controls and procedures to guard against theft and diversion." 21 C.F.R. § 1301.71(a). Among other requirements, registrants must design and operate a system for identifying and reporting suspicious orders. *See* 21 C.F.R. § 1301.74(b)). As this Court has already held, opioid distributors are obliged to identify and report suspicious orders, and to refrain from shipping suspicious orders until they can determine, through investigation and due

[4] Red flags include, for example: (1) "pattern prescribing," meaning multiple patients presenting prescriptions for the same drugs, the same quantities from the same physician without any kind of variability or change considering the different patients that come into the pharmacy, thus suggesting that the physician prescribes in a factory-like manner; (2) prescriptions for excessively high dosages of drugs or excessively high quantities from a particular prescriber; (3) prescriptions written by a prescriber whose DEA license is expired, suspended, or who has been indicted on drug-related charges; (4) drug remedies outside the prescriber's ordinary area of practice (e.g., pediatrician writing long-term, high dosage opioid prescription for adult patient); (5) prescriptions written by medical providers located in distant states; (6) prescriptions presented by individuals who traveled from distant locations; (7) prescriptions paid for using cash, particularly if cash payments are from the same patient; (8) prescriptions for drug cocktails (e.g., opioid/ benzodiazepine, opioid/benzodiazepine/muscle relaxer, etc).; (9) many patients receiving the same strength (lack of individualized dosing); (10) unusual patient groupings for a particular prescriber or location (e.g., many patients under the age of 35 presenting prescriptions for opioids); (11) early and/or frequent refills for opioids; (12) unusual proportion of controlled vs. non-controlled prescriptions substance prescriptions at a particular store or from a particular prescriber; and (13) information that other pharmacies are refusing to fill a particular doctor's prescriptions.

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diligence, that the order is not likely to be diverted. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019). Indeed, this Court held:

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

Id. at *9.

Defendants have similar duties with respect to dispensing. The CSA prohibits a pharmacy from filling a prescription unless it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice."[5] 21 C.F.R. § 1306.04(a);

[5] "The CSA also defines the term "valid prescription" to mean "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner." 21 U.S.C. 829(e). The *legitimacy* or *validity* of a prescription is thus distinct from the question of its medical *necessity*. *See* Plfs'. Memo. ISO Mot. for Partial Summ. J. Concerning Defs'. Statutory and Regulatory Duties, Index. No. 400001/2017, No. 400008/2017, No. 400016/2018, NYSCEF Doc. No. 2849. (Plaintiffs here attach their Memorandum of Law in Support of Motion for Partial Summary Judgment Concerning Defendants' Statutory and Regulatory Duties, NYSCEF Doc. No. 2849. Plaintiffs filed this motion in the New York Coordinated action on January 14, 2020, setting forth plaintiffs' arguments regarding Defendants' duties to protect against diversion under the CSA when acting both in their wholesale distributor and retail dispensing capacities. Defendants' response to the NY motion is due February 12, 2020. In the MDL, this Court granted plaintiffs' Motion for Partial Summary Adjudication on the issue of the Defendants' wholesale distributor duties under the CSA on August 19, 2019. Dkt. # 2483.) Although legitimacy and medical necessity are quite different, it is not the case, as Defendants have sometimes suggested, that legitimacy can be reduced to a single inquiry as to whether the prescription is "valid" or whether the doctor actually saw the patient. Rather, as the DEA has repeatedly required, pharmacies must assess and resolve *all* indicia that a prescription has not been issued for a legitimate medical purpose. *See, e.g., Medicine Shoppe-Jonesborough v. Drug Enforcement Administration*, 300 F. App'x 409, 412-13 (6th Cir. 2008); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018).

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see also Ohio Admin. Code § 4729-5-30(A). These obligations run not only to pharmacists, but to pharmacies and to their corporate parents, *See United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, (N.D. W.Va. Dec. 19, 2016); *United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189 (E.D. Ky. 2017); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala.1996); *United States v. Poulin*, 926 F. Supp. 246, 250, 253 (D. Mass. 1996); *United States v. Robinson*, No. 12-20319-CIV, 2012 WL 3984786 (S.D. Fla. Sept. 11, 2012).[6]

Under the CSA and its regulations, "[a] pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Medic-Aid Pharmacy; Revocation of Registration* 55 FR 30043-01, 1990 WL 328750 (Dep't of Justice July 24, 1990); *see also* Ohio Admin. Code § 729-5-20. "[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions." *East Main Street Pharmacy; Affirmance of Suspension Order*, 75 FR 66149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010). As the Sixth Circuit has recognized, once suspicions about the legitimacy of a prescription are, *or should be* raised, a pharmacy has an obligation *not* to dispense until the "red flags" indicative of diversion are resolved. *See Medicine Shoppe-Jonesborough v. Drug Enforcement Administration*, 300 F. App'x 409 (6th Cir. 2008); *see also United States v. Henry*, 727 F.2d 1373, 1378-79 (5th Cir.1984); *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145 (D.D.C. 2012). Indeed, the *Medicine Shoppe* Court held, "[B]y filling [red-flag] prescriptions anyway. . . the pharmacy not only violated its duties under federal (and state) law to

[6] This is so regardless of whether Defendants themselves were registered as pharmacies. *See* 21 U.S.C. § 841 (prohibiting *any person* from selling controlled substances other than in accordance with the provisions of the statute and its regulations).

ensure that only proper prescriptions were filled but also put public health and safety at risk." *Id.* at 413.

Thus, the duty of a pharmacy is analogous to that of a distributor. Just as distributors may not ship suspicious orders without proper due diligence to determine that diversion is not likely, so, too, pharmacies may not fill prescriptions in the presence of unresolved red flags about the legitimacy of the prescription or the prescriber. Indeed, the Drug Enforcement Administration ("DEA") has recognized that, as the last line of defense, pharmacies play a critical role in protecting against diversion.[7]

Given these duties under the CSA and state regulations, the issues for trial must necessarily focus, as the Court correctly noted during the January 29, 2020 hearing, on whether Defendants implemented and enforced effective policies and procedures to protect against diversion of the dangerous and addictive drugs that they chose to distribute and dispense. If they had such policies, when did they put them in place, were they adequate or just "window dressing," and, if in place, did they adhere to them. *See* Tr. at 12 (Jan. 29, 2020). Plaintiffs will show that, to the extent Defendants turned a blind eye to indicia of diversion in crafting their policies and procedures, to the extent they intentionally employed policies and practices which made diversion *more* likely, not less likely, to the extent they had information at their disposal that allowed them to detect suspicious orders or red-flag prescriptions, but elected not to use it to protect against diversion (instead using it to increase sales), and to the extent Defendants shipped suspicious orders and filled red-flag prescriptions without engaging in the due diligence necessary to determine that such orders and prescriptions were unlikely

[7] *See* DDM00455828, February 2018 NACDS Presentation, "Opioids and DEA Compliance," at p. 32 ("DEA Response… Pharmacies: 'last line of defense'").

to be diverted, Defendants not only violated state and federal law, but also caused and/or substantially contributed to the public nuisance of the opioid crisis.

D. Proof

Plaintiffs expect that their proof will be of two types: (1) proof that focuses on the nature of Defendants' policies, procedures, training, and practices; and (2) proof in the form of analysis of the aggregate data that was available to Defendants and that they failed to use to protect against diversion.

The first category of proof will show that Defendants failed to implement policies to protect against diversion; failed to collect or make use of available data to assist them in doing so; failed to implement, effectively or at all, such policies as they had; failed to monitor and/or control those implementing the policies and procedures; failed to enforce, or to allocate resources sufficient to enforce, their policies; failed to perform appropriate due diligence when information that raised, or should have raised, suspicions, was available; and indeed, adopted policies and practices that made diversion *more* likely, rather than less likely. This type of proof is qualitative, rather than quantitative, and is based on information from the Defendants with respect to the policies, practices, and procedures they had concerning both distribution and dispensing, and whether, and to what extent, their policies and procedures were actually adequate, implemented, and followed.

The second type of proof involves quantitative analysis of aggregate data that shows what Defendants knew (or could have known with the information available to them) and what they actually did with respect to distribution and dispensing of opioids. As the Court knows, with respect to distribution, Plaintiffs have analyzed the ARCOS data from the DEA to determine what suspicious wholesale orders Defendants could have and should have identified at the time the suspicions arose. Plaintiffs intend to perform a similar analysis of Defendants' aggregate dispensing data to determine

what "red flags" Defendants could have and should have identified.[8] This analysis will parallel, to some extent, the types of analyses that the CVS Defendants themselves have acknowledged, indeed have bragged, that chain pharmacies are uniquely situated to perform. *See Abusive Prescribing of Controlled Substances – A Pharmacy View,* N. Engl. J. Med. 2013, 369:9989-991 (Sept. 12, 2013). Together, these proofs will establish that Defendants repeatedly failed to provide effective controls against diversion with respect to both distribution and dispensing.

Plaintiffs believe these proofs will also establish that Defendants' CSA violations were a substantial contributing factor in creating and maintaining the opioid epidemic that continues to plague the nation, the State of Ohio, and the bellwether counties. Plaintiffs intend to establish this causal connection in multiple ways. First, Defendants' liability for public nuisance in the plaintiff jurisdictions turns not on whether Defendants failed to block one or a few individual suspicious wholesale orders or red-flag prescriptions, but on whether Defendants' failure to implement effective policies and procedures to block and resolve indications of diversion meant the number of unresolved suspicious orders and red-flag prescriptions was of a sufficient magnitude to constitute an unreasonable interference with a public right. The volumes of suspicious orders, or red-flag prescriptions, that Defendants shipped or, in the case of prescriptions, filled without performing due diligence, are in and of themselves sufficient to support a finding of a causal connection. *See Southwood Pharmaceuticals, Inc.; Revocation of Registration,* 72 FR 36487-01, 36503, 2007 WL 1886484 ("Respondent's

[8] Defendants argue that there is no need for them to produce their dispensing data because Plaintiffs have access to the OARSS data. Because Defendants' duties are based on what they knew or should have known at the time, Plaintiff should have access to the historic information Defendants had available, not the information that Plaintiffs or Defendants can recreate now using the OARSS database. As Defendants have argued, the OARSS database has different information than the Defendants had available at the time dispensing was done.

distribution of 77 million dosage units of hydrocodone which were likely diverted caused extraordinary harm to the public health and safety."). In that circumstance, evidence that certain specific orders or prescriptions were not in fact diverted will not and cannot refute the inference of causation. Given the magnitude of diversion that occurred, and given sufficient volumes of suspicious orders and red-flag prescriptions, the causal link between the two does not turn on showing that every one of those prescriptions was diverted. A factfinder can readily conclude that a sufficient percentage *was* diverted, without the need to identify specifically which ones.

Virtually every prescription pill that was diverted from legitimate use (all but those lost to pilferage) reached Plaintiffs' communities through a prescription that was sold through a pharmacy. Plaintiffs' proofs will show that, despite their legal obligation to do so, Defendants failed to properly protect against diversion of the opioids that passed through their hands at both the wholesale and the retail level; that the Defendants' failure to meet their legal responsibilities resulted in large volumes of suspicious wholesale orders and red-flagged prescriptions being filled without adequate controls against diversion; that these volumes alone are sufficient to demonstrate that those suspicious orders Defendants shipped and red-flagged prescriptions Defendants filled were a substantial contributing factor to the opioid epidemic. Whether Defendants could now find enough evidence to show that some of the suspicions and red flags raised then could be cured today, has no bearing on whether Defendants complied with the law at the time and, as discussed above, that is insufficient to refute Plaintiffs' proof of causation.

Dated: February 7, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2020, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/ Peter H. Weinberger
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